Unitary supplementary protection certificate for plant protection products

2023/0126(COD) - 28/02/2024 - Text adopted by Parliament, 1st reading/single reading

The European Parliament adopted by 406 votes to 192, with 9 abstentions, a legislative resolution on the proposal for a regulation of the European Parliament and of the Council on the unitary supplementary protection certificate for plant protection products.

As a reminder, the proposed regulation lays down rules on the unitary supplementary protection certificate for plant protection products protected by a European patent with unitary effect and subject, prior to being placed on the market as a plant protection product, to an administrative authorisation procedure.

The European Parliament's position adopted at first reading under the ordinary legislative procedure amends the Commission's proposal as follows:

Conditions for obtaining a unitary certificate

A unitary certificate should be granted by the Office on the basis of a basic patent if, in each of the Member States in which that basic patent has unitary effect, all of the following conditions are fulfilled:

(a) the product is protected by that basic patent in force;

(b) a valid authorisation to place the product on the market as a plant protection product has been granted in accordance with Regulation (EC) No 1107/2009;

(c) the product has not already been the subject of a certificate, nor of a unitary certificate;

(d) the authorisation is the first authorisation to place the product on the market as a plan protection product.

Lodging of an application for a unitary certificate

The application for a unitary certificate should be lodged with the Office. If the application for a unitary certificate complies with the provisions of the Regulation, the Office should publish it in the register as soon as possible.

Opposition

Within a period of 2 months following the publication of the examination opinion in respect of an application for a unitary certificate, any person may file with the Office a notice of opposition to that opinion. The notice of opposition should include any evidence the opponent relies on in support of the opposition.

In cases where several oppositions have been filed against an examination opinion, the Office should deal with the oppositions jointly and issue one single decision in respect of all oppositions filed.

The Office should issue a decision on the opposition, including a detailed reasoning for that decision, within 6 months, unless the complexity of the case requires a longer period.

If the opposition panel considers that no ground for opposition prejudices the maintenance of the examination opinion, it should reject the opposition and notify the opponent of its decision, and the Office should mention this in the Register.

Full transparency should be ensured throughout the whole opposition proceeding, which shall be open, whenever possible, to public participation.

Competent national authorities

On a request made to the Office, any competent national authority may be appointed by the Office as a participating office in the examination procedure. Once a competent national authority is appointed, that authority should designate one or more examiners to be involved in the examination of one or more applications for unitary certificates based on relevant expertise and sufficient experience required for the centralised examination procedure.

Examination panels

The assessments should be conducted by an examination panel including one member of the Office as well as two examiners from two different participating competent national authorities. When setting up an examination panel, the Office should ensure the following:

- **relevant expertise and sufficient experience** in the examination of patents and supplementary protection certificates, ensuring, in particular, that at least one examiner has a minimum of five years of experience in the examination of patents and supplementary protection certificates;

- where possible, **geographical balance** amongst the participating offices.

Grant of a unitary certificate or rejection of the application for a unitary certificate

After the period during which an appeal or an opposition may be filed has expired without any appeal nor opposition being filed, or after a final decision on the merits has been issued, the Office should implement without undue delay the examination opinion by granting a unitary certificate or rejecting the application, as applicable.

Appeals

Parliament underlined the need to **safeguard procedural rights** and ensure a complete system of remedies.

In case of an appeal, a written statement setting out the grounds of appeal, including the evidence supporting those grounds, should be filed within 3 months of the date of notification of the decision. Any reply to the statement of grounds of appeal should be submitted in writing no later than three months from the date of the filing of the statement of grounds of appeal. The Office should, where applicable, fix a date for oral proceedings within three months of the filing of the reply or within six months following the filing of the statement of grounds of appeal, whichever is earlier. The Office should issue a written decision within three months of the date of the oral hearing or of the filing of the reply to the statement of grounds of appeal, as applicable.

When appointing members of the Boards of Appeal in matters concerning applications for unitary certificates, due consideration should be given to their previous experience in matters concerning supplementary protection certificates or patent law.

Taking of evidence

If the Office or the relevant panel considers it necessary for a party, witness or expert to give evidence orally, it should issue a summons to the person concerned to appear before it. Where an expert is summonsed, the Office or the relevant panel, as the case may be, should verify that that expert is free of any conflict of interest.

Evaluation

By five years after the date of application, and every five years thereafter, the Commission should evaluate the implementation of this Regulation and present a report on the main findings to the European Parliament and the Council. As part of that evaluation, the Commission should assess the feasibility and benefits of establishing a central authorisation procedure for plant protection products under the European Food Safety Authority.